6P 3732
TC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|---|---|---|
| Appln. No. | : | 10/007,812 |
| Applicant | : | ROBERT S. SUPINSKI |
| Filed | : | November 8, 2001 |
| Title | : | PATELLA REPLACEMENT APPARATUS |
| Group Art Unit | : | 3732 |
| Examiner | : | David C. Comstock |
| Docket No. | : | 011072 |

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on

this 16th day of September, 2005.

Buchanan Ingersoll, P.C.

**REQUEST FOR RECONSIDERATION**

Pittsburgh, Pennsylvania 15219

September 16, 2005

Commissioner for Patents
Post Office Box 1450
Alexandria, Virginia 22313-1450

Sir:

In the Office Action dated June 16, 2005, the Examiner rejected all the pending claims under Section 102 or Section 103 based upon a single reference, United States Patent No. 5,019,104, to Whiteside et al. The claims had been allowed over this reference by Examiner Bonderer who originally examined this application. Claims 1 through 21 of the pending application were copied from U.S. Patent No. 6,146,432 to Cohen et al. where another Examiner concluded that these claims were patentable over the Whiteside reference.

Whiteside discloses a patellar prosthesis formed from a rigid, preferably metallic backing portion 12 having "integrally formed securing pegs 13 which are provided to secure the

prosthesis to the posterior side a resected patella." Col. 2, lines 16-21. At column 2, lines 22-24 the reference says "the anterior surface of metallic attachment portion 12 can be provided with a porous layer such as sintered metal microbeads 14 to allow for tissue growth." This statement tells us that the metallic attachment portion 12 is not porous and that the metallic portion 12 does not allow for tissue growth. If portion 12 were porous it would not be necessary to provide porous layer 14.

The Whiteside patella prosthesis also has a polymeric surface layer 15 which is pressure molded onto the attachment portion 12 fully covering the upper covered surface of the attachment layer.

Claims 1, 8, 15 and 22 are the only independent claims that were pending. All the claims are directed to a patella replacement device having a first member and a second member. In the most recent Office Action the Examiner has identified metallic backing portion 12 in Whiteside as corresponding to the first member in applicant's claims and polymeric surface layer 15 as corresponding to the second member in applicant's claims.

Claims 1 and 8 both require

> "a first member fabricated from a porous metal material and having a rounded fixation surface for implantation in the patella region of a patient with said porous metal allowing biological fixation to said patella region of said patient, said first member having a relatively flat surface opposite said rounded surface and having at least one aperture therein,"

Whiteside's backing member 12 does not meet this limitation because backing member 12 is not porous and does not allow biological fixation to the patella region. Whiteside specifically teaches that a porous layer 14 is applied to member 12 to allow for tissue growth. So, one skilled in the art reading Whiteside would understand that member 12 is not porous. Furthermore, the

porous layer 14 is applied by Whiteside "to allow for tissue growth." From that statement one skilled in the art would conclude that the backing member 12 does not allow for tissue growth and hence does not allow for biological fixation to the patella region as required by applicant's claims. Moreover, Whiteside also says that pegs 13 are provided to secure the prosthesis to the posterior side of a resected patella. Without those pegs the Whiteside device could not be fixed to the patella region of the patient and would not be operable. In applicant's device the porous structure allows "bone and tissue to grow into the component and anchor the prosthesis." Specification page 9, lines 2-3. This biological fixation is quite different from the mechanical attachment using pegs that is taught by Whiteside. These differences in structure, use and function of the first member in applicant's claims and the backing element 12 in the reference are such that claim 1 and 8 are neither anticipated by nor obvious from the Whiteside reference.

In addition to requiring a first member and a second member, claim 15 requires:

> "an annular ring secured about said first member, said ring having a central aperture, an extending flange portion surrounding said first member and a plurality of apertures about a periphery thereof; and . . . a peripheral gap is formed between said first and second members . . . "

The Whiteside device does not meet either of these limitations. There is no gap between backing portion 12 and surface portion 15. There is also no structure separate from backing portion 12 and surface layer 15. Hence, only a first member and a second member are present in the Whiteside prosthesis. In rejecting claim 15 the Examiner states, "The reduced width outer peripheral portion of the device can be characterized as an integral ring or annulus." There is nothing in the Whiteside reference which refers to the combined outer regions of the backing portion 12 and surface portion 15 as an outer ring. Even if such portions could be viewed as an

annular ring they are integral portions of the backing element 12 and surface portion 15. These portions are not "secured about said first member" as required by claim 1. It is only through impermissible hindsight that one can find an annular ring in the Whiteside device and when found that ring does not meet the requirements of claim 15. Because neither the annular ring nor the peripheral gap required by claim 15 are taught or suggested in the Whiteside patent, claim 15 is not anticipated or obvious from this reference.

Claim 22 requires first and second members together with "a porous coating containing at least one bone growth material and applied to at least a portion of at least one of said first member and said second member." Page 9, line 17, through page 10, line 4 of the specification teach that bone growth materials include hydroxyapatite, human bone particles, bovine bone particles, ground coral and calcium sulfate. Although the Examiner rejected claim 22 under Section 102. the Office Action does not identify any structure in the Whiteside device that the Examiner regards as "a porous coating containing at least one bone growth material." Whiteside discloses "a porous layer such as sintered metal microbeads 14 to allow for tissue growth," (col. 2, lines 23-24) but there is no teaching or suggestion of any material being contained in that layer. The Examiner states that would have been obvious to form the Whiteside device of materials comprising hydroxyapatite, human bone particles, bovine bone particles, ground coral or calcium sulfate since it has been held to be within the general skill of a worker in the art to select a known material or the basis of its suitability for the intended use as a matter of obvious choice. Office Action, page 3. The stated purpose of Whiteside's layer 14 is "to allow for tissue ingrowth." That can be and has been accomplished by a porous layer. But, claim 22 requires more than a porous layer. Claim 22 requires a material that promotes bone growth to be within

that porous layer. There is no teaching of either a bone growth material or that bone growth should be promoted in the Whiteside reference. A reference does not support a conclusion of anticipation or obviousness where the reference does not teach all the limitations of a claim. *In re Fine*, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1988).

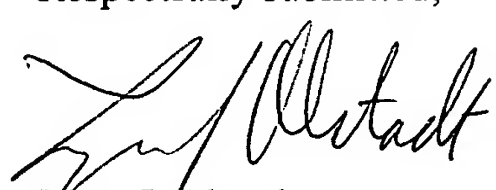
For an invention to be anticipated and properly rejected under Section 102 every element of the clam must be found in a single cited reference. For a rejection to be proper under Section 103 there must be something present in the teaching of the reference to suggest to one skilled in the art that the claimed invention would have been obvious.

> "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, it to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303, 312-313 (CAFC 1983), 721 F.2d 1540, 1553

Because the Whiteside reference does not teach or suggest a patella replacement device having the porous metal first member required by claims 1 and 8 or the annular ring and peripheral gap required by claim 15 or the porous coating containing at least one bone growth material required by claim 22, these claims are patentable over this reference. The remaining claims depend from claims 1, 8, 15 or 22 and are patentable because the parent claims are patentable.

Reconsideration, allowance and declaration of an interference with U.S. Patent No. 6,146,423 are respectfully requested.

Respectfully submitted,



Lynn J. Alstadt
Registration No. 29,362
BUCHANAN INGERSOLL, P.C.
301 Grant Street
Pittsburgh, Pennsylvania 15219

Attorney for Applicant

(412) 562-1632